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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE: BOARD OF PHARMACY

DATE AND TIME: Wednesday, February 15, 2017 9:30 am

PLACE: Conference Room A, 2nd Floor Cannon Building

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: March 15, 2017

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President Hooshang Shanehsaz, R.Ph., Professional Member, Vice President Bonnie Wallner, R.Ph., Professional Member Kimberly Robbins, R.Ph., Professional Member Tejal Patel, PharmD, Professional Member Jay Galloway, Public Member Gayle MacAfee, Public Member

MEMBERS ABSENT

Samantha Nettesheim, Pharmacist Administrator

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III Michelle McCreary, Pharmacist Compliance Officer David Mangler, Director

ALSO PRESENT

Tim DeRose Ryan de Lorraine Anthony Gabriel Michelle Maylie Amakoe Ajavon Abhishek De Craig Clarke

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Ms. MacAfee and seconded by Mr. Shanehsaz to approve the meeting minutes for January 18, 2017 with corrections. The motion carried.

UNFINISHED BUSINESS

Statutory and Regulatory Discussion -

<u>Telemedicine Pharmacy Regulations Change</u> – A motion to table this agenda item until the March 15, 2017 meeting was made by Mr. Shanehsaz seconded by Mr. Galloway. The motion unanimously carried.

<u>3PL Licensure</u> – Ms. Kelly provided similar laws and regulations from the states of California and Wyoming for the Board to review. A motion was made by Mr. Shanehsaz seconded by Ms. MacAfee to have Ms. Kelly draft proposed changes to regulation 8.0 to include virtual distributors for review during the next meeting March 15, 2017.

PRESIDENT'S REPORT

Ms. Esposito provided the following report:

NABP Convention May 20-23, 2017: After reviewing the bylaws only current pharmacy board members or chief administrative officers qualify to serve as delegates or alternate delegates. Therefore our request for Christine Mast to go as our delegate is not possible. I would like us to review the Delegate/alternate delegates under other business.

DPS Health Fairs: I have received information on contacts from Sussex County to help with the three scheduled Health Fairs being held at Greenwood Library, Beebe Healthcare is providing two Nurses for each session to help with the screenings and we have received a number of items to be given as incentives for attending all three sessions.

CE Audits: I spent a few days going through the CE Audits with Christine and was very surprised at some of the material that was sent in. A number of people sent in CE Certificates for Patient Safety and Immunization only-no proof of 30 credits, some submitted the credits in multiple emails requiring time to find duplicate certificates, some sent in 293 credits requiring each to be reviewed to find the required ones, others sent in less than 30 credits even though the audit letter was specific. I am very grateful to Christine and her staff for the amount of work they did to organize the massive amount of documents that the audit requires them to review. Many individuals only sent in the NABP monitor report, or listings from Pharmacists letter. The Walgreens course certificates do not indicate CE hours or ACPE accreditation numbers on them. We may need to review this process to ensure everyone understands what the audit letter requires. Mr. Shanehsaz stated that the ACPE codes that are provided to courses have an identifier number that provides the type of CE that is taught. He stated he would ask NABP for the glossary of codes. This should assist in the ability to more easily identify courses taken and help expedite the audit by using a log instead of numerous certificates. A motion was made by Mr. Shanehsaz seconded by Ms. Patel to allow the CPE monitoring log to be provided for audit purposes instead of certificates. The motion carried.

Resignation of Public Member: It is with regret that I inform you of the Resignation of Julie Wheatley as Public Member from Sussex County. Her expertise and insight will be missed. We wish her well as she moves out of Delaware. Ms. Esposito commended Ms. Wheatley for her time on the Board.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications: Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005043	Robert	Rudolf	Svenson
A1-0005044	Chima		Ihedigbo
A1-0005045	Kerri	D	Bevacqua
A1-0005046	Stefan	A.	Kolodij
A1-0005047	Zishan	S.	Khan
A1-0005048	Messay		Addis

Pharmacist Intern:

A7-0002444	Emily	Paige	McCormick
A7-0002445	Ifra	Vagar	Sharief
A7-0002446	Jacqueline Emily	C.	Von Bulow
A7-0002447	Nicholas	M.	Paulson
A7-0002448	Michelle	Trinh	Hoang

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist/Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001944	Gordian Medical II, Inc. dba Better Balance Pharmacy
A9-0001945	Promise Pharmacy, LLC
A9-0001946	On Track Rx, LLC
A9-0001947	Schraft's 2.0
A9-0001948	Jiffy Scripts RX
A9-0001949	Innovative Rx, LLC
A9-0001950	Emerson Pharmacy, Inc.
A9-0001951	Paragon Healthcare Specialty
A9-0001952	Avella of Deer Valley, Inc. #38
A9-0001953	Village Fertility Pharmacy, LLC
A9-0001954	Wirx Pharmacy
A9-0001955	Rx Care of Lady Lake, Inc dba Benzer Pharmacy
A9-0001956	Giant Eagle Pharmacy #0221
A9-0001957	Gulf Coast Scripts, LLC
A9-0001958	Walgreens #16198
A9-0001959	Triad Compounding Pharmacy
A9-0001960	Delaney Pharmacy, LLC

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Non Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0002376	Ollin Phamaceutical, LLC
A4-0002377	Mechanical Servants, LLC
A4-0002378	Nielsen Biosciences, Inc.
A4-0002379	Valmed Pharmaceutical, Inc.
A4-0002380	Masters Pharmaceutical, LLC dba River City Pharma
A4-0002381	Graxcell Pharmaceutical, LLC
A4-0002382	Smith Drug Company, Division of J M Smith Corporation

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000145 Contour Medical Supply, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0001009 Raajipo, LLC

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy application. The motion unanimously carried.

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Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

None

Pharmacist-In-Charge Interviews

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to amend the agenda to add the following for PIC interviews. The motion unanimously carried.

Pharmacist-In-Charge - Amakoe Ajavon, Rite Aid, Lewes, De.

Ms. Robbins conducted Pharmacists/Consultant Pharmacists in Charge interviews:

Consultant Pharmacist – Ryan de Lorraine, Manor Pharmacy, Newark, De.

Pharmacist In Charge - Amakoe Ajavon, Rite Aid, Lewes, De.

Board Review of Facility Applications

Invotex, LLC. Dba: Fusion Pharmaceuticals (FL) - A motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

<u>Continuing Education Review</u> – A letter on behalf of: Anne Melanie B. Martin requesting an extension for the submission of continuing education requirements due by January 30, 2017. A motion to provide an extension until June 30, 2017 was made by Mr. Shanehsaz seconded by Ms. Patel. The motion unanimously carried.

Pharmacist & Pharmacy - Discussion/Action Items

Dispensing of Naloxone – Jamie Mack, Division of Public Health – tabled until March 15, 2017 by the request of the presenter.

COMMITTEE REPORTS

Legislative - Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and Gayle MacAfee

Mr. Shanehsaz stated that he had contacted Mr. Randy Farmer from DHIN and he stated he would make himself available to attend a future meeting with the Board once the Executive Secretary position is filled.

Continuing Education — Bonnie Wallner, Tejal Patel:

No Report

Consumer Affairs - Jay Galloway

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

No Report

Controlled Substance Liaisons - Tejal Patel, Hooshang Shanehsaz, Jay Galloway:

Ms. Patel stated that the new Opioid Prescribing regulations go into effect on April 1, 2017. These regulations are primarily prescribing practices that must be followed by the practitioners. She spoke of the limitation of prescribing only 7 days on the first prescription. Ms. Kelly stated that there are new proposed regulations pending that would provide exemptions to the 7 day supply which include; if the prescriber meets all the requirements during the initial visit they do not have to do it again, and if the patient is discharged from inpatient/outpatient surgical center they would be exempted as well. Ms. Robbins asked if the patient is switching from one pain management practitioner to another would the new pain management practitioner have to start from the beginning. The answer to that was determined to be "yes" if it is a new patient for the practitioner and all regulations should be completed and followed. Mr. Mangler stated that the Medical Society fully understands the intent that all of the requirements should be completed for an acute pain prescription. The Prescription Monitoring Program should be utilized, provide counseling on the risks and benefits of opioid use, and utilize the informed consent agreement.

INSPECTION & PMP REPORT - Michelle McCreary, Samantha Nettesheim

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Ms. McCreary stated that the biggest thing on her plate currently is the Rite Aid stores that remain in transition. In addition to the Rite Aid transition she has completed the following inspections:

- 1 Retail Pharmacy Inspection
- 1 Researcher Inspection

Mr. Mangler reported that he and Ms. Kelly reviewed the current HID due to the change in ownership from HID to Appriss to ensure there would be nothing to preclude discussions with Appriss on a new contract.

NEWSLETTER UPDATES

None

BOARD CORRESPONDENCE

Ms. Esposito read the following correspondence, Resignation Letter Received - Ms. Julie Wheatley

Center for Interventional Pain Spine, LLC., Dr. Philip S. Kim M.D., Letter – Dr. Kim raised concerns of professionalism with regard to Pharmacists' insinuating to his patient(s) that they are drug addicts or doctor shopping based on information the pharmacist has access to in the Prescription Monitoring Program. Dr. Kim would like pharmacists to contact physicians when they have these concerns and ask that they not make these assumptions nor share these assumptions with the patient. The pharmacist does not have the patient history to refer to and should not make these assumptions solely on medications in the Prescription Monitoring Program. He stated there are many instances a patient in pain management and also has an injury or surgery where additional pain medication is necessary for a short period of time and this is allowed even with a pain management agreement. Dr. Kim suggests more communication with practitioners when these concerns arise. The Board suggested that the Board's newsletter provide guidance on professionalism and cultivate open communication between pharmacists and practitioners. The Board also suggested that a member be a liaison between the Board of Medical Licensure and the Board of Pharmacy to cultivate more communication. Mr. Galloway will put together a letter to be included in the next newsletter from the Board for review at the next meeting.

Mr. Mangler wanted to clarify to everyone that the new opioid prescribing regulations that take effect on April1, 2017, there will more than likely be prescriptions for more than 7 days' supply. Pharmacists should not be under the impression that a prescription for more than 7 days should not be filled, it should. Pharmacists are not the gate keeper of the opioid prescribing regulations the practitioner (prescriber) is. Practitioners can write for more than 7 day's supply once they have completed certain requirements under the regulations.

Onsite 340B, Innovative Pharmacy Services Solutions Letter –

Ms. Esposito open discussion regarding the letter received. The Board requested that a letter be sent stating that the letter received referenced Title 16 however the pharmacy regulation is under title 24. Title 24 Regulation 12.2, the policy and procedures manual is required to be kept on site and readily available during an inspection.

Impax Letter - Epinephrine Auto Injector

Ms. Esposito read the letter received that stated a generic alternative was now available at a lower cost.

Richard Mazzoni Letter -

Ms. Esposito read the letter however; the Board cannot provide support for solicitation of any kind. There is no response needed.

OTHER BUSINESS BEFORE THE BOARD

Elimination of Conviction Questions on Applications that Require Criminal History Reports for Application – these questions are being removed from all new applications where a mandatory criminal history record is

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required for licensure, since it is redundant. Other applications without the mandatory requirement will remain. These questions will continue to be asked during the renewal process for all licensees.

A motion to amend the agenda to Discuss the Delegate Selection for the annual NABP meeting in May was made by Ms. Robbins and seconded by Ms. Patel. The motion carried.

Discussion of the Delegate for the NABP Meeting in May -

The Board discussed who should be listed as the Board approved voting delegates. The Board recommended that Ms. Esposito be the 1st delegate, Ms. Patel be the 2nd Alternate Delegate (as she will be attending), and Mr. Shanehsaz would be 3rd Alternate Delegate.

PUBLIC COMMENT

Ryan de Lorraine, R.Ph. spoke regarding issues identifying the correct patient in the PMP and taking the time to review all identifying information. This is particularly an issue for twins and many patients with like names. He wanted to make the Board aware so future upgrades may correct this issue.

NEXT SCHEDULED MEETING

The next meeting is scheduled for March 15, 2017 at 9:30 Am., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Shanehsaz and seconded by Ms. Wallner at 11:12 am. The motion unanimously carried.

Respectfully submitted,

Christine Mast

Administrative Specialist III

Liaison, Board of Pharmacy